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Giorgio Rosati

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EXAMINER

GUPTA, VANI

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,802	Applicant(s) ROSATI, GIORGIO	
	Examiner VANI GUPTA	Art Unit 3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-17 is/are pending in the application.
- 5a) Of the above claim(s) 12-17 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-11 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/28/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1 – 11 in the reply filed on July 11, 2011 is acknowledged.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Paragraph [0099] contains the phrase "Prom." Examiner believes that this is a typographical error on the Applicant's part, and that Applicant meant to indicate "*From*."

Claim 2 includes "external viewing apparatus" in its limitations. However, the specification does not include a reference to this external viewing apparatus. While Examiner understands that this refers to a monitor for displaying images, appropriate corrections to the specification to address this lack of antecedent basis is still required.

Claim 4 includes a "sensor," "interface," and "output," in its limitation. There is no proper description of these limitations in the disclosure. While is understandable from the claim what interface and output may be, it is not clear what this sensor may be. An appropriate correction, such amending the specification without introducing new matter to include a description of these items is required.

Claim Objections

3. Claim 1 is objected to because of the following informalities: line 6 contains the spelling "centre" for the word center. Although Examiner understands that this spelling conforms to

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convention and practices in Europe, it is suggested that Applicant amend the claim so that the spelling of the word fits/conforms with the standard US practices for US patent applications.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the claim limitation “means for calculating position and inclination of the axis of the hole relative to at least one between the reference and the pointing system and to move the terminal to provide the surgical instrument guidance means with an inclination same as the inclination of the axis of the hole uses the phrase “means for” or “step for” or a non-structural term coupled with functional language, but it is modified by some structure, material, or acts recited in the claim. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function because it seems that its “proper/correct” movement/placement of the head is dependent upon the ability of the external apparatus to perform *its* job properly or correctly.

Additionally, claim limitation “means for calculating position and inclination of the axis of the hole relative to the reference and to move the head to provide the means for guiding the

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surgical instrument with an inclination same as the inclination of the axis of the hole” uses the phrase “means for” or “step for” or a non-structural term coupled with functional language, but it is modified by some structure, material, or acts recited in the claim. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function because it seems that proper/correct calculation is dependent upon the ability of the means for guiding the surgical instrument to perform *its* job properly or correctly.

Regarding Claim 3, the claim limitation “means for moving the terminal close to an end of the nail containing the hole, to allow said external apparatus to take an image of the end of the nail containing the hole and of a reference integral with the terminal” uses the phrase “means for” or “step for” or a non-structural term coupled with functional language, but it is modified by some structure, material, or acts recited in the claim. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function because its “proper/correct” movement/placement of the terminal is dependent upon the ability of the external apparatus to perform *its* job properly or correctly.

Additionally, claim limitation “means for calculating position and inclination of the axis of the hole relative to at least one between the reference and the pointing system and to move the terminal to provide the surgical instrument guidance means with an inclination same as the inclination of the axis of the hole” uses the phrase “means for” or “step for” or a non-structural term coupled with functional language, but it is modified by some structure, material, or acts recited in the claim. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function because it seems that the performance of the means for calculating positional and inclinational information is dependent upon the structure that moves

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the terminal to; and further, it seems the performance of the structure that moves the terminal has is dependent upon the performance of the surgical guidance means.

If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant may amend the claim so that the phrase “means for” or “step for” or the non-structural term is clearly **not** modified by sufficient structure, material, or acts for performing the claimed function, or present a sufficient showing that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed function.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant may amend the claim so that it will clearly not invoke 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112, sixth paragraph.

5. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 4 claims a sensor that is connected via an interface to an output (presumably the screen, itself, which displays an “output;” a.k.a. image) of the external viewing apparatus (presumably a monitor – see objection to specification above). However, there is no written description of what this sensor is or what it entails.

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6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 claims that s sensor is connected via the interface to the output of the external viewing apparatus. However, it is not clear what this sensor is or how it connected to the interface to the output of the external viewing apparatus. It is not also clear what exactly this interface is, or what the output of the external viewing apparatus is.

Thus, for purposes of examination, Examiner interprets sensor as a way to “connect” the monitor to an imaging device and “retrieve” data that will be displayed on the interface or display screen of the external viewing apparatus or monitor. Please refer to the rejection just above for more details on this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 – 4 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Wilson et al. (US 6, 656,189 B1).

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Regarding Claim 1, Wilson et al. (hereinafter Wilson) suggests a pointing apparatus for correct positioning of distal locking screws of an intramedullary nail comprising a hole, the pointing apparatus comprising:

means for receiving one or more images of a portion of the nail (**61**) to be fixed with the screws, the one or more images showing the hole (**8**); means for processing the one or more images to obtain coordinates of the center of the hole and inclination of an axis of the hole; and means for positioning an instrument (**trocar - (30); drill - (50)**) in correspondence with the axis, and align the instrument with the axis (col. 2, line 1 – col. 3, line 5; col. 6, line 31 – col. 7, line 31).

Regarding Claim 2, Wilson suggests the pointing apparatus as claimed in claim 1, further comprising:

a head (**70**) which includes a reference (**20**) to be viewed by an external viewing apparatus (**71**), and means (“aiming guide”) for guiding a surgical instrument, trocar (**20**) and/or drill (as described in col. 5, l. 28 – col. 7, line 9);

means for moving said head close to an end of the nail containing the hole, to allow said external viewing apparatus to take an image of the end of the nail containing the hole and of the reference (see rejection of claim 1; col. 5, ll. 61 – 67; **figs. 6 - 8**);

means for reading the image and calculate position and inclination of the axis based on shape and dimensions of the hole shown in the image (col. 5, line 27 – col. 6, line 57);

means for reading the image and calculate relative position and inclination of the reference, and consequently of the head, based on shape and dimensions of the reference (col. 5, ll. 1 – 38);

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means for calculating position and inclination of the axis of the hole relative to the reference and to move the head to provide the means for guiding the surgical instrument with an inclination same as the inclination of the axis of the hole (see above citations).

Regarding Claim 3, Wilson suggests the pointing apparatus as claimed in claim 1, further comprising:

a reference system (protective sleeve, (30)) to be viewed by an external of apparatus;

a pointing system ((33), of the trocar) which contains a housing (the trocar itself);

a terminal (“distal end of trocar,” col. 5, line 22), fitted with surgical instrument guidance means, the terminal capable of being designed to receive the pointing system via a quick release coupling associated with the housing;

means (“aiming guide”) for moving the terminal close to an end of the nail containing the hole, to allow said external apparatus to take an image of the end of the nail containing the hole and of a reference integral with the terminal (see rejections of claims 1 and 2);

means for reading the image and calculate position and inclination of the axis based on shape and dimensions of the hole shown in the image (see rejections of claims 1 and 2; “concentric circles”);

means (monitor) for reading the image and calculate relative position and inclination of the reference, and consequently of the terminal, based on shape and dimensions of the reference; and means for calculating position and inclination of the axis of the hole relative to at least one between the reference and the pointing system and to move the terminal to provide the surgical instrument guidance means with an inclination same as the inclination of the axis of the hole (see also col. 4, l. 56 – col. 5, line 41).

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The above may apply to the drill surgical instrument as well; the terminal being the shank (52); the pointing system being the tip (53); the housing being the drill itself. See also col. 5, line 50 – col. 7, l. 31).

Regarding Claim 4, in light of the objection to the specification for lack of antecedent basis for the sensor and in light of the 35 USC 112 first paragraph rejection for lack of written description and second paragraph, Examiner makes the following rejection:

Wilson suggests the pointing apparatus as claimed in claim 2 , wherein the means for reading comprises a sensor (a computer-electronic connector or another way for connectivity between electronic devices) electronically communicating with the imaging device so that the monitor receives or senses data so that the image data is outputted via the interface or display screen of the external apparatus. These aspects are known and/or inherent to the art of using monitors to display image data. External viewing apparatus (X-ray monitor, (71)) would inherently comprise an interface or display screen; and would inherently comprise connectivity to the imaging device to “sense” the image data from the imaging apparatus for displaying the image data via the display screen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson as applied to claims 1 - 3 above.

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Regarding Claim 5, Wilson suggests the pointing apparatus as claimed in claim 2, wherein the reference is integral with the head and comprises one or more radiopaque bodies of known shape, dimensions and position, incorporated in the head, such that the reference works in conjunction with the (imaging) head such that the radiopaque markers of the reference show up on the images being displayed on the monitor.

With respect to a *physical* integration, generally speaking, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to integrate radiopaque markers with an imaging head, since it has been held that forming in one piece an article, which has formerly been formed in two pieces and put together involves only routine skill in the art. See *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). It also is known generally that would entail mere arrangement of parts, which does not receive any patentable weight because it would not produce any unexpected results. See *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). One of ordinary skill in the art may do one of the above to assist in alignment of the imaging head with the reference system. One may also provide additional radiopaque markers on the imaging head (that is, in addition to the ones on the reference system), since it known that perform mere duplication of parts such as radiopaque markers are well known within the ordinary skill in the art, and unless a new unexpected results is produced by providing radiopaque markers on the imaging head as well as on the patient, this feature has no patentable weight. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Regarding Claim 6, with respect to the pointing apparatus as claimed in claim 3, wherein the reference system (33) is separate from the terminal, Applicant should note that it would have been obvious to one of ordinary skill in the art at the time the invention was made to

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make the reference system (33) separate from the terminal of the trocar, since it has been held that constructing formerly integral structures into various, separate, elements involves only routine skill in the art. *See Nerwin v. Erlichman*, 168 USPQ 177, 179. Once separate, the terminal is capable of being connectable to the reference system via a quick release coupling and is capable of being fitted with means for guiding a surgical instrument in a known position relative to at least one between the reference system and the pointing system.

Regarding Claim 7, Wilson suggests the pointing apparatus as claimed in claim 2 wherein the reference comprises a plurality of radiopaque elements of known shape, dimensions and position (see rejections of claims 2 and 3).

Regarding Claim 8, with respect to the pointing apparatus as claimed in claim 7 wherein the radiopaque elements are spheres, this would be an obviousness matter of design choice. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant). Furthermore, since applicant has not disclosed that providing spherically shaped radiopaque markers solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the size and/or shape of radiopaque markers provided by Wilson.

Regarding Claim 9, with respect to the pointing apparatus as claimed in claim 7 wherein the radiopaque elements are located at vertices of polygons, Applicant should note that this entails mere arrangement of parts, which does not receive any patentable weight because it would not produce any unexpected results. See *In re Japikse*, 181 F.2d 1019, 86 USPQ 70

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(CCPA 1950). Nonetheless, it would be prima facie obvious to modify Wilson to provide such an arrangement so that one may optimize on localizing/placement of the surgical instrument in the hole(s) of the nail. With respect to providing the markers at vertices of polygons *of known dimensions*, see In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Regarding Claim 10, Wilson suggests the pointing apparatus as claimed in claim 3 wherein the terminal and the reference system is *capable of being* mounted on a support comprising a plurality of numerically controlled actuators designed to control translation of the terminal and the reference system according to at least two linear directions orthogonal to one another and to control rotation of the terminal and the reference system around at least two non-parallel axes. In the present instance, the claim is only claiming functionality of the reference system – that is should be connectable to a support comprising various/multiple features such as actuators. The support and its components itself is not being positively recited. Additionally, generally speaking, providing actuators that are capable of controlling movement of devices such as the terminal would be known by one of ordinary skill of art. Furthermore, Wilson provides teachings for manual translation, alignment, rotation, etc. (col. 5, line 34 - 41; col. 6, ll. 11 - 30). Therefore, it would have been obvious to one of ordinary skill in the art to modify Wilson to provide “automated” means for performing translation, alignment, rotation, etc., and doing so

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would not receive any patentable weight, since it has been held broadly that providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art, and involves only routine skill in the art. See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

Regarding Claim 11, Wilson suggests the pointing apparatus as claimed in claim 2 further comprising a sterile hood, capable of being fitted to the head, the sterile hood capable of being designed to cover supports and any other parts coming into contact with an operating field of the pointing apparatus (col. 6, ll. 1 – 2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777